MAY 27 2004

SECTION II

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K040411

Submitter:
Microgenics Corporation
46360 Fremont Blvd
Fremont, CA 94538
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Contact Person:

David Casal, Ph.D.
Vice-President, Clinical, Regulatory and Quality Affairs
Telephone: (510)-979-5012
Facsimile: (510) 979-5212

Preparation Date:

February 17, 2004

Device Information:

Device Classification Name:	Radioimmunoassay, Oxycodone
Common/Usual Name:	Oxycodone Immunoassay Test System
Proprietary Name:	DRI® Oxycodone Assay
Regulation Number:	21 CFR§862.3650
Regulatory Name:	Oxycodone test system
Product Code:	DJG
Regulatory Class:	Class II

Predicate Devices:

The DRI® Oxycodone Assay is substantially equivalent to the Rapidone-Oxy Test (K014101) manufactured by American Bio Medica Corp (Columbia, MD) for its general intended use.

Device Description:

The DRI® Oxycodone Assay is supplied as liquid ready-to-use homogeneous enzyme immunoassay. The assay uses specific antibodies that can detect oxycodone and oxymorphone without significant cross-reactivity to other opiate compounds. The assay is based on competition between oxycodone labeled with glucose-6-phosphate dehydrogenase (G6PDH), and free oxycodone present in the urine sample for a fixed amount of specific antibody binding sites. In the absence of free oxycodone in the sample, the specific antibody binds the drug labeled with G6PDH and causes a decrease in enzyme activity. This phenomenon creates a direct relationship between the drug concentration in urine and enzyme activity. The enzyme activity is determined spectrophotometrically at 340 nm by measuring the conversion of nicotinamide adenine dinucleotide (NAD) to NADH.

Intended Use:

The DRI®Oxycodone Enzyme Immunoassay is intended for the qualitative and semi-quantitative detection of oxycodone in human urine.

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography /mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used.

Comparison to Predicate Device(s):

The information provided in this pre-market notification demonstrates that the DRI® Oxycodone Assay is substantially equivalent to the Rapidone-Oxy Test (K014101) manufactured by American Bio Medica Corp (Columbia, MD) for its general intended use.

Device Characteristics	Subject Device	Predicate Device (K014101)
Intended Use	The DRI®Oxycodone Enzyme Immunoassay is intended for the qualitative and semi-quantitative detection of oxycodone in human urine. The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography /mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used.	RapidOne-OXY Test is a one-step, lateral flow immunoassay for detection of oxycodone in urine. RapidOne-OXY Test is intended for the qualitative detection of oxycodone in human urine ate 100 ng/mL. RapidOne-OXY Test is intended for professional use. It is not intended for over the counter sales to non-professionals. The assay is easy to perform, but should not be used without proper supervision. This immunoassay is a simplified qualitative screening method that provides only a preliminary result for use in determining the need for additional confirmatory testing, i.e., gas chromatography/mass spectrometry (GC/MS). The RapidOne-OXY Test provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a more confirmed analytical result. Gas chromatography /mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used.
Analyte	Oxycodone	Oxycodone
Matrix	Urine	Urine
Calibrator Form	Liquid	None
Calibrator Levels	Five (5) Levels (0, 100, 300, 500 and 1000 ng/mL)	None
Storage	2°C to 8°C until expiration date	Room temperature or refrigerated (2 to 8°C).
Stability	Until expiration date noted on vial label and Package Insert for Kit and reconstituted reagents.	Until expiration date noted on vial label.

Summary:

The information provided in this pre-market notification demonstrates that the DRI® Oxycodone Assay is substantially equivalent to the Rapidone-Oxy Test (K014101) manufactured by American Bio Medica Corp (Columbia, MD) for its general intended use. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available predicate device as confirmed by gas chromatography/mass spectrometry, an independent analytical method.. The information supplied in this pre-market notification provides reasonable assurance that the DRI® Oxycodone Assay is safe and effective for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 27 2004

David Casal, Ph.D.
Vice-President, Clinical, Regulatory and Quality Affairs
Microgenics Corp.
46360 Fremont Blvd
Fremont, CA 94538

Re: k040411
Trade/Device Name: DRI® Oxycodone Assay
DRI® Oxycodone Calibrators
DRI® Oxycodone Controls
Regulation Number: 21 CFR 862.3650
Regulation Name: Lithium test system
Regulatory Class: Class II
Product Code: LAS, DLJ,DJG
Dated: February 17, 2004
Received: March 2, 2004

Dear Dr. Casal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

K040411

510(k) Number (if known): ~~K040458~~

Device name: DRI® Oxycodone Assay

Indications for Use:

The DRI® Oxycodone Assay is intended to be used for the qualitative and semi-quantitative determination of the presence of oxycodone in human urine at cutoffs of 100 and 300 ng/mL. The assay provides a simple and rapid analytical screening procedure to detect oxycodone in human urine.

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography /mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used.

The DRI® Oxycodone Calibrators are used to calibrate the DRI® Oxycodone Assay in human urine.

The DRI® Oxycodone Controls are used to qualify the DRI® Oxycodone Assay in human urine.

Prescription Use __X_____ AND/OR Over-the Counter Use_____
(Part 21 CFR §801 Subpart D) (21 CFR §807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040411